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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,945	06/08/2001	Ulf Smith	45069	8408

466 7590 10/29/2003

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	14

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/875,945	SMITH, ULF	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No. 13) filed on May 30, 2003 has been entered.

2. Claims 1-39 are canceled. New claims 40-55 were added.

Response to Arguments

3. Applicant's response to the office action (Paper No.13) is fully considered and deemed persuasive in part.

4. With respect to the rejection made in the previous office action under 35 U.S.C. 112, first paragraph, Applicant's arguments with respect to claims 1-6 are considered but are found not persuasive because of the following reasons:

Applicants argue that cancellation of claims 1-39 by the instant amendment (Paper No.13) and providing new claims directed to an isolated SEQ ID No.3 and its homologous sequences which exhibit at least 70% homology with SEQ ID No.3, used in a screening system and as a marker for compounds exhibiting insulin regulating properties would obviate the rejection. These arguments have been fully considered and found not persuasive because the claims, as exemplified by independent claims 40, 47, are drawn to sequences comprising at least 70% homology to SEQ ID No. 3. Applicant has described only one species in this genus, the species which is 100% identical to the particular SEQ ID NO. Applicant has not disclosed any sequences which are less than 100% identical to this sequence. In Lilly, the District court noted that "The human insulin cDNA, for example, differs from the rat insulin cDNA by four codons. " Regents of the Univ. of California v. Lilly, 39 U.S.P.Q.2D 1225 (SD Indiana 1995). Thus, there was significant sequence information in Lilly, with a much greater degree of homology

than Applicant is claiming. A comparison of the human (NM_000207) and Rat insulin (NM_019129) cDNAs in Genbank by a blast alignment shows that these two sequences are, in fact, 81% identical. Thus, Lilly presents nearly the same exact situation as the current claims and in that case, the court found the claims to lack written description. Further no specific biological function for SED ID No.3 is provided by the amendment except for the intended use of the sequence as a marker in screening compounds exhibiting insulin properties and no structural information is provided that specifies wherein the sequence the biological function resides. Since the claims 1-6 are cancelled by this amendment the rejection is withdrawn herein. However, the rejection is re written below addressing the new limitations in the instant new claims.

5. With reference to the rejection under 35 USC 102(a), Applicants' arguments have been fully considered, and found not persuasive. Applicants argue that the prior art (BIREN et al.) teach a sequence homologous to SEQ ID NO.3 and fail to teach a screening system or the sequence as a marker for compounds exhibiting insulin regulating properties. This argument is fully considered, however, it is noted that the claims are directed to an isolated nucleic acid and not directed for the intended use of the product. It is noted that as MPEP 2112 states, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). In the instant case since both sequences are identical (that of the claimed invention and of Biren et al.) and yield the same result thus the intended use is inherent. However the rejection is withdrawn inview of the

cancellation of the claims1-6 and the rejection is rewritten below addressing the new claim limitations.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

6. The following is the rejection made in the previous office action under 35 USC 112 first paragraph:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-55 are rejected under 35U.S.C. 112, first paragraph, as containing subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to an isolated, substantially purified nucleotide sequence, comprising SEQ ID No. 3 and homologous sequences thereof, wherein said homologous sequence exhibits at least 70% homology, said nucleotide sequence is a screening system and is a marker for compounds exhibiting insulin regulatory properties. Further the dependent claims recite nucleotide sequences exhibiting at least 90% and 98% homology to SEQ ID No.3. This large genus of homologous sequences exhibiting at least 70%, 90% and 98% homology is represented in the specification by the named SEQ ID No.3. Thus, applicant has expressed possession of only one species in a genus, which comprises hundreds of millions of different possibilities. The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised

guidelines for written description.) Here, no common elements or attributes of the homologous sequences are disclosed. With regard to the sequences exhibiting at least 70% or greater homology comprising SEQ ID No. 3, this is insufficient to demonstrate identity of all specific fragments of the claimed SEQ ID No.3 with its homologous sequences exhibiting 70%, 90%, and 98% homology, wherein the structural limitation of the sequences is not disclosed. Instant claims are overly broad in the recitation of " comprising" since no guidance is provided as to wherein the SED ID NO.3 or its homologous sequences the biological function resides. Further no information is given in the specification regarding a methodology to determine such common elements or attributes. Further, there is no description of homologous fragment(s) binding to a compound that exhibits insulin regulating properties. The general intended use of the sequence in a screening system as a marker for compounds exhibiting insulin regulating properties, does not constitute a biological function of the said SEQ ID NO.3. The specification provides insufficient written description to support the genus encompassed by the claims.

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the nucleotide sequence of the disclosed SEQ ID NO. 3 is described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that: "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception or written description of nucleic acid molecules comprising modified by addition, insertion, deletion, substitution or inversion with the disclosed 70% , 90% and 98% homology to SEQ ID No.3 and no correlative sequence in the claimed product.

Accordingly, the specification does not provide a written description of the invention of claims 40-55.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 40-41, 43-55 are rejected under 35 U.S.C. 102(a) as being anticipated by Birren et al. (Whitehead Institute/ MIT center for Genome Research, submitted on October 15, 1999).

With reference to the instant claims 40-41, and 47-49, Birren et al. teach an isolated nucleic acid sequence clone comprising the SEQ ID NO. 3 of the instant claims (see sequence alignment) and has 100% homology with SED ID NO. 3.

With reference to the instant claims 43-46, 51-55, the nucleic acid sequence of Birren et al. could hybridize under stringent conditions because it has 100% homology to SEQ ID NO.3. The nucleic acid sequence of Birren et al. meets the limitation regarding the homology of at least 70%, 90%, or 98%, because it has 100% homology with the instant SEQ ID NO. 3. As discussed above in response to arguments, as MPEP 2112 states, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). In the instant case since both sequences are identical (that of the claimed invention and of Biren et al.) yield the same result thus the intended use is inherent. Thus the disclosed nucleic acid sequence of Birren et al. meets the limitations in the instant claims.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
October 20, 2003

JEFFREY FREDMAN
PRIMARY EXAMINER